



Posted: 06/16/2010NF

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DIVISION OF PROFESSIONAL REGULATION

PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, May 19, 2010 at 9:30 a.m.
PLACE:	Conference Room 1st floor, Cannon Building 861 Silver Lake Blvd., Dover, DE
APPROVED:	June 16, 2010

MEMBERS PRESENT

Sandra Robinson, R.Ph, Professional Member, President
Geoffrey N. Christ, Esq., R.Ph, Professional Member, Vice President
Howard Simon, R.Ph, Professional Member
Don Holst, R.Ph, Professional Member
Sebastian Hamilton, R.Ph, Professional Member
Joli Martini, R.Ph, Professional Member
Carolyn Calio, Public Member
David W. Dryden, R.Ph., J.D., Executive Secretary

MEMBERS ABSENT

David Bonar, Public Member

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

Allison Reardon, Deputy Attorney General
Nancy Fields, Administrative Specialist II
James Kaminski, R.Ph, Pharmacist Administrator
James Collins, Division Director

ALSO PRESENT

Penelope Tsilimidos
Eunjin Yang
Cheryl Heiks
Sandra Guckian
Mark R. Currie
Al Helmeczi
Trent Beach
Phil Anderson
Marie Meyer
Tiffany Sorey
Suzanne Raab-Long
Les Bensen
Whitney Swears

CALL TO ORDER

Ms. Robinson called the meeting to order at 9:30 a.m.

REVIEW OF MINUTES

A motion was made by Mr. Simon, seconded by Mr. Christ, to approve the April 21, 2010 minutes as presented. The motion unanimously carried.

PRESIDENT'S REPORT

On April 21, 2010, Ms. Robinson attended the DSHP Annual Banquet at White Clay Country Club.

On May 5, 2010, Ms. Robinson testified at the Health & Human Development Committee of the House of Representatives regarding the wording change in Title 16 of the "licensed" pharmacy technician to "pharmacy technician" for HB 382. She also received a copy of the amendment added by the State Police to HB 235. A copy of the bill has been distributed for discussion.

On May 10, 2010, Ms. Robinson attended the Regulation 7 Committee meeting in Dover.

On May 13, 2010, Ms. Robinson attended the DPS Convention & Awards Banquet at the Deerfield Golf & Tennis Club in Newark.

On May 14, 2010, Ms. Robinson participated in the state medication take-back program at Kent General Hospital in Dover.

NEW BUSINESS

A motion was made by Mr. Simon, seconded by Mr. Holst, to move down the agenda to Pharmacist-In-Charge (PIC) and Consultant interviews. The motion unanimously carried.

Mr. Simon conducted the PIC interviews for Marie Meyer, Penelope Tsilimidos, Leslie A. Benson, and Whitney Swears. He also conducted the Pharmacist Consultant interview for Eunjin Yang. The PIC interview for Sumera DeSilva was tabled until the next meeting.

A motion was made by Mr. Hamilton, seconded by Ms. Martini, to go back to Unfinished Business on the agenda. The motion was unanimously carried.

UNFINISHED BUSINESS

Legitimate Medical Purpose – Internet Pharmacy Proposal

This proposal is still pending.

Drug Disposal and Distribution Review

Mr. Christ and Mr. Kaminski attended the drug disposal in Sussex County. They reported that overall it was very well received; however, for future reference, there are a few areas that will require improvement. Mr. Christ suggested that each site have guidelines to follow because they faced issues such as not being informed about the separation of a few of the items such as inhalers and creams. They also did not have a representative present from the Division of Health, and lastly they had to wait an extra two hours for Clean Harbor to do their part.

Mr. Hamilton and Mr. Dryden attended the drug disposal in New Castle County. They reported that it was well received and very successful as well. They took in large quantities of narcotics. They were aware to separate the inhalers etc. The Nurses Association and New Castle County Police were available to assist them.

Ms. Robinson attended the drug disposal in Kent County. They were very busy. A Dover Police Officer and two DEA agents and staff from Bayhealth were there to assist; however, the main obstacle was the construction going on at Bayhealth. Ms. Robinson also saw a few areas for improvement, especially parking for those returning medications. She had to wait for Clean Harbor to complete their reporting. She suggested having a meeting with the Division of Public Health to work out some of the details, and possibly have a review and feedback session regarding the program.

The Board had previously approved all of the changes to HB 235; however, on May 5, 2010, Ms. Robinson was handed an amendment to the bill at Legislative Hall. The amendment was issued by the Delaware State Police. The primary issues are that they do not want to have to report to a “lower” regulating board regarding taking back drugs and they want to continue being able to take-back drugs at the police headquarters if dropped off by citizens. The Board does not agree that they are the “lower regulating Board”.

Mr. Christ read Title 11, section 9200, which are the laws concerning law enforcement. The only thing mentioned about drug take-back is having the right to confiscate drugs. Public Safety and the Office of Narcotics and Dangerous Drugs also do not do take-backs or disposals and it was thought that they do not have future plans of doing so. The Board has to decide what whether to pull the bill out or let it go through. Mr. Kaminski made a suggestion to pull the bill because he believes the DSP wants an exception to hold events.

Mr. Collins, Division Director, came in to talk with the Board about HB 235. He advised the Board that he spoke with leadership at Homeland Security. They are concerned that this bill will impede their ability to take back drugs if in the future they decide to do so. He stated that the primary goal of this bill is to have the ability to get drugs off the streets and it really shouldn't matter who gets them off the streets. He advised the Board that it had four choices regarding the bill. They could accept the amendment, reject the amendment, amend the amendment, or pull the bill out of this session.

A motion was made by Mr. Holst, seconded by Mr. Hamilton, to accept the amendment. Three members voted yes. Four members voted to oppose. The motion did not carry.

Mr. Christ recommends that setting some type of minimum standards and procedures would help. The Board and Counsel are concerned about the statement that ALL law enforcement can take back drugs without a Pharmacist's expertise.

A motion was made by Mr. Simon, seconded by Mr. Hamilton, to accept the amendment as long as the language was narrowed to say that there will be a limiting clause regarding law enforcement at the disposal. The motion unanimously carried.

Mr. Christ, Ms. Robinson, Mr. Dryden, and Ms. Reardon will work on language to amend the amendment.

Regulation 14 Review - Administration of Injectable Medications

Mr. Holst advised that another meeting will be scheduled in the near future.

Prescription Monitoring Program (PMP)

Mr. Collins stated that the PMP bill passed in the Senate but still has to pass the House. Rules and vendors have to be established. The grant application was submitted in order to get the funds. They are continuing to work on ways to put the information into a state clearing house.

Regulation 7 Review

Mr. Dryden, Chair for the Committee, reported that the Committee had met and determined that Ms. Reardon should review 24 Del. Code 2523 and determination. Future meetings will include Non-Pharmacy veterinary oriented personnel.

State of Emergency Issue Update

Mr. Dryden has and will continue to attempt to speak to officials regarding this issue.

Signing of the Order for Regulations 1, 5, 9, 10 & 19

A motion was made by Mr. Simon, seconded by Ms. Martini to accept the final regulations. The motion unanimously carried. The final regulations will be posted June 11, 2010.

NEW BUSINESS

Ratification of Pharmacist Licenses

A motion was made by Mr. Holst, seconded by Mr. Simon, to ratify the licensures issued by the Division of Professional Regulation for the following individuals:

Sharon A. Hartman
Meredith C. Gove
Gina L. Rice
Honorine Quenum-Diagne

The motion was unanimously carried.

CMC Dispensing

Mr. Helmeczi spoke to the Board regarding pilot and the use and placement of a dispensing device pilot at Christiana Care Health Services during a renovation. He advised that the device is in a secured place right outside of the pharmacy doors within the hospital. He will monitor it for 6 months as a pilot and bring all reports back to the Board.

A motion was made by Mr. Holst, seconded by Mr. Simon to accept the remodeling application, to accept the pilot for the dispensing device, and to have reports provided to the Board regarding the status. Mr. Hamilton abstained. The motion carried.

Michael Tulish Consent Order

After reviewing and discussion the consent agreement submitted by the state, a motion was made by Mr. Hamilton, seconded by Mr. Christ to reject the Consent Agreement. The motion unanimously carried. Ms. Gadbois will be advised of the Board's decision.

Committee Reports

Joint Practice Committee – Don Holst and Howard Simon – No report.

Physician's Assistant Report – Sebastian Hamilton, R.Ph: - Mr. Hamilton informed the Board via report that the council met on Tuesday, May 4, 2010. The council approved two new applications for licensure, four applications for controlled prescriptive authority, and no applications for non-controlled prescriptive authority. The next meeting is scheduled for Tuesday, June 2, 2010.

Newsletter – Sandy Robinson, R. Ph., David Dryden, R.Ph., J.D, and Joli Martini, R. Ph.: Mr. Dryden advised that he put regulation 4.10 in the last newsletter.

Legislative – Sandy Robinson, R.Ph, Howard Simon, R.Ph, Sebastian Hamilton, R.Ph, Don Holst, R.Ph, Geoffrey Christ, R.Ph., Esq., and David Dryden, R.Ph., J.D.: Ms Robinson reported that on May 5, 2010, HB 235 was tabled, HB 382 passed at the Committee meeting and is now ready for the House to review.

Mr. Holst will attend a meeting with DSP and DSHP regarding collaborative care.

Continuing Education – Sandy Robinson, R. Ph., Michael Hertzfeld, Geoffrey Christ, R.Ph., Esq., and Joli Martini, R. Ph.: No report.

Consumer Affairs – Carolyn Calio, Michael Hertzfeld, and David Bonar: No report.

Professional Liaison – Sandra Robinson, R.Ph. and Joli Martini, R.Ph: Ms. Robinson stated that there will be a DPS meeting at the Levin Center in Smyrna on May 25, 2010.

Ms. Robinson has no information regarding upcoming events for DSHP.

MPJE Study Committee – Don Holst, R.Ph, Sebastian Hamilton, R.Ph, and James Kaminski: Mr. Hamilton stated that questions were submitted regarding e-prescribing. Mr. Dryden stated that the Board had concerns with the “select all” format; therefore, Delaware does not have to follow that format.

Controlled Substance Liaisons – Geoffrey Christ, Howard Simon, and Dave Dryden: A Committee meeting is scheduled for May 26, 2010 to go over all the topics that Mr. Collins spoke about such as the PMP program and tamper-proof prescription pads.

Substantially Related Crimes Committee - Geoffrey Christ, Howard Simon, Allison Reardon, and Dave Dryden: No report.

Board Correspondence

Mr. Dryden reported that he contacted NABP on April 22, 2010 regarding Board concern with the new “select all answers” format. NABP was put on notice that they did not want this type of question on the Delaware examination. NABP noted this in their file and also stated that these types of questions could be “crossed out in October’s review.

Correspondence to Xttrium laboratories, Inc dated April 22, 2010 regarding Xttrium Laboratories, Inc. Board determination and notification.

Correspondence from NABP dated May 13, 2010 regarding Staff Training.

Correspondence from NABP dated May 13, 2010 regarding DEA Ruling “E-Prescribing” of Controlled Substances & MPJE State Item Review.

Correspondence from NABP dated 05/14/10 regarding the Recall of OTC Liquid Medicines for Children and Infants.

Inspection Report

Inspections were conducted at four pharmacies, which included four Controlled Substance Authority inspections, one clinic and one veterinarian. Three practitioner non-compliant prescription blanks were found. One follow up for a non-compliant prescription blank was received. No further action is necessary.

When deficiencies are found during the inspection process or audits of controlled substances are not acceptable, the office requires written responses from the pharmacist-in-charge (PIC) or notifies the facility that a re-inspection will occur. There are three outstanding requests for a response at present. One outstanding request was changed to a complaint and submitted to the investigative unit. Three facilities are on hold for re-inspection.

The office received a remodel application for a pharmacy which would continue to operate from the same area as the remodeling was being done. The work would occur during and after the pharmacy closed for the day. A pharmacist would be on duty at all times to monitor construction workers and to ensure that no unauthorized persons gain access to prescription drugs or patient files. Video of the entire remodel project will be archived at the store for review if needed.

Inspections' of medical gas dispensers is still a priority for the office and is an ongoing process.

A Christiana Care Health Services Pharmacist will be packaging and labeling drugs in offices at the Wilmington Hospital Annex, 1400 Washington St., Wilmington, Delaware. Drugs will be ordered, per policy, by the Wilmington Hospital Department of Pharmacy Services. These drugs will then be transported via Christiana Care internal transport to the offices across the street. In an e-mail to our office dated March 31, 2010, she is confirming and requesting approval from the Delaware State Board of Pharmacy to label and occasionally break down bottles of medications on the Ryan White Title B Formulary. She understands that all dispensing and prepacking rules associated with Regulation 6 will be followed. These drugs will be packaged and labeled in a practitioner-run clinic and transported by licensed pharmacists to additional practitioner-run clinics within that program. These medications will be dispensed to uninsured, HIV-infected, Delaware residents per Ryan White Title B Regulations. After review by our office, this procedure meets the requirements of Regulation 6.

The office had an inquiry from a privately owned pharmacy that is interested in opening an infusion center with a pharmacy in the facility. The facility would staff a pharmacist to dispense and a registered nurse to provide infusions of intravenous medications and injections of specialty drugs. Prescriptions would only be filled for patients who would have their medication administered at the facility. There would be no practitioner relationship with this facility. The pharmacist would have total responsibility of the pharmacy area which would be secured when the pharmacist is not present. If dispensing directly to the patient the institution would have to be licensed as a pharmacy. Licensure could possibly occur under Regulation 20.0 Specialty Institutional Pharmacy Licenses. The application would have to be reviewed by the office prior

to licensure. For nurse administration in a facility it was suggested to contact the Office of Health Facility Licensing and Certification and the Board of Nursing.

Other Business before the Board

Mr. Simon advised that there was a May 7, 2010 News Journal article regarding Bruce Costa working as a pharmacy technician after his pharmacist license was revoked or suspended. This may be something the Board should address.

Public Comments

Ms. Guckian made an inquiry to the Board to get some clarification on HB 235, specifically lines 16 and lines 67 & 68. She thought that a change was needed to change the word dispenser to the pharmacy DEA # so there would be a clearer distinction if it is a person. Ms. Reardon stated that Title 24, section 2502 defines a person, to include the facility.

Mr. Anderson stated that June 1, 2010 is the official day that e-prescribing is supposed to begin and asked if a signature is required for this. He suggested that the Medical Society may need to do a press release to say that the program is not ready yet. Mr. Dryden stated that this issue would be addressed by the Controlled Substance Committee meeting on May 26, 2010.

Mr. Holst asked if long term care for hospice is exempt from a verbal emergency prescription. Mr. Dryden will review this issue.

Next Scheduled Meeting

The next meeting is scheduled for June 16, 2010 in Conference Room A.

Adjournment

A motion was made by Mr. Hamilton, seconded by Mr. Holst to adjourn the meeting. The motion unanimously carried. The meeting adjourned at 11:53 a.m.

Respectfully submitted,



Nancy Fields
Administrative Specialist II